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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,204

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Simon Bates

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08/03/2010

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EXAMINER

KILPATRICK, BRYAN T

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,204	Applicant(s) BATES ET AL.	
	Examiner BRYAN T. KILPATRICK	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The arguments/remarks filed on 18 May 2010 have been entered and fully considered.
2. Instant claims 1 and 4-14 are pending currently.

Terminal Disclaimer

The terminal disclaimer filed on 05 August 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 7,372,941(issued from application no. 10/635,113) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Objections

Claim 10 is objected to because of the following informalities: the word "power" (in line 3, after the previous amendment) appears to be a misspelling of "powder." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1797

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2003/0123057 (LEMMO et al.), and further in view of "Structure by diffraction of X-rays of liquid gallium between +50 and 110°C," *Physica Status Solidi A*, 23(1); 135-145; 1974 (BIZID et al.) – IDS filed 08 August 2007.

Independent instant claims 1 and 4, and corresponding dependent instant claims 5-10 and 14 recite a method comprised of comparing a PDF trace of a first sample of a substance, wherein the substance is a pharmaceutical, with a PDF trace of a second sample of the substance to identify any similar or different solid forms. The claimed method further employs a computer-readable medium having instructions for performing the claimed method. LEMMO et al. discloses a method of screening an array of samples and determining if any share spectral features, which is similar to comparing diffraction patterns, in paragraphs [0017] and [0021]-[0022], as well as the use of X-ray diffraction analysis in paragraph [0141]. LEMMO et al. further discloses that compounds of interest for analysis includes pharmaceuticals in paragraph [0076], and recites the use of a computer in a system for detecting similarities among a plurality of samples in claims 8-21.

LEMMO et al. does not expressly disclose the use of pair distribution function, PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample in the English Abstract. Since both LEMMO et al. and BIZID et al. focus of the field of X-ray diffraction, it would have been obvious to one of ordinary skill in the art to employ PDF with X-ray diffraction analysis for the purpose of comparing liquid and crystalline forms of a sample (English Abstract of BIZID et al.).

Instant claim 11 recites a method comprised of comparing a PDF trace of a plurality of samples of a substance with one or more PDF traces of known solid forms of

Art Unit: 1797

the substance for identifying any substances in the sample that have a new solid form. LEMMO et al. discloses in paragraph [0018] the screening of an array of samples for the presence of a particular form of a compound-of-interest. In addition, paragraph [0203] presents an example of the analysis done using a known sample.

LEMMO et al. does not expressly disclose the use of pair distribution function, PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample in the English Abstract. Since both LEMMO et al. and BIZID et al. focus of the field of X-ray diffraction, it would have been obvious to one of ordinary skill in the art to employ PDF with X-ray diffraction analysis for the purpose of comparing liquid and crystalline forms of a sample (English Abstract of BIZID et al.).

Instant claim 12 recites a method comprised of providing and grouping a plurality PDF traces of substances by similarity into groups through hierarchical cluster analysis. Paragraph [0021] and [0023] of LEMMO et al. discloses a method of analyzing and calculating similarities of a plurality of samples via clustering.

LEMMO et al. does not expressly disclose the use of pair distribution function, PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample in the English Abstract. Since both LEMMO et al. and BIZID et al. focus of the field of X-ray diffraction, it would have been obvious to one of ordinary skill in the art to employ

PDF with X-ray diffraction analysis for the purpose of comparing liquid and crystalline forms of a sample (English Abstract of BIZID et al.).

Instant claim 13 recites a system comprised of a means of comparing a PDF trace of a first sample of a substance with a PDF trace of a second sample of the substance to identify any similar or different solid forms. Paragraph [0020] of LEMMO et al. discloses a system for analyzing samples using a method as disclosed in paragraphs [0017] and [0021]-[0022] that encompasses analyzing a plurality of samples using spectral data to identify similarities.

LEMMO et al. does not expressly disclose the use of pair distribution function, PDF. However, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases of a gallium sample in the English Abstract. Since both LEMMO et al. and BIZID et al. focus of the field of X-ray diffraction, it would have been obvious to one of ordinary skill in the art to employ PDF with X-ray diffraction analysis for the purpose of comparing liquid and crystalline forms of a sample (English Abstract of BIZID et al.).

Response to Arguments

Applicant's arguments/remarks filed 18 May 2010 have been fully considered but they are not persuasive.

Applicant states on p. 3-4 of the remarks that, “Nowhere does *Bizid* suggest that the PDF could be used, as recited in the instant claims, to compare different samples of a substance to establish whether the substances are the same or different solid forms. Further, there is no indication in the references cited that the PDF could be used on pharmaceutical substances, which gallium clearly is not.” As previously stated above, BIZID et al. discloses an X-ray diffraction study wherein PDF is employed for comparative analysis of different physical phases – liquid gallium and crystalline phases - of a gallium sample in the English Abstract. LEMMO et al. discloses a method of screening an array of samples and determining if any share spectral features, which is similar to comparing diffraction patterns, in paragraphs [0017] and [0021]-[0022], as well as the use of X-ray diffraction analysis in paragraph [0141]. LEMMO et al. discloses that compounds of interest for analysis include pharmaceuticals in paragraph [0076]. The combination of LEMMO et al. and BIZID et al. is used to show that pair distribution function can be employed with X-ray diffraction analysis of compounds of interest such as pharmaceuticals or gallium.

Applicant states on p. 5 that, “Indeed, one of ordinary skill in the art would have no incentive to modify *Lemmo*, which teaches the use of x-ray powder diffraction data, to compare, for example, solid forms with the PDF analytical technique of *Bizid*, which: (a) is directed to gallium (not a pharmaceutical substance), (b) focuses on the analysis of the internal structure of gallium as a function of temperature, and (c) teaches that the PDF yields a different conclusion about the gallium than x-ray powder diffraction.” As previously stated, since both LEMMO et al. and BIZID et al. focus of the field of X-ray

Art Unit: 1797

diffraction, it would have been obvious to one of ordinary skill in the art to employ PDF with X-ray diffraction analysis for the purpose of comparing liquid and crystalline forms of a sample (English Abstract of BIZID et al.). Furthermore, the differences between PDF and X-ray powder diffraction observed by BIZID et al. were due to differences associated with the phase of the sample; BIZID et al. states in the last sentence of the English Abstract that the PDF of liquid gallium “presents more marked analogies with the atomic distributions of metastable crystalline forms than with that of the stable form.”

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRYAN T. KILPATRICK whose telephone number is

Art Unit: 1797

(571)270-5553. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. T. K./
Examiner, Art Unit 1797

/Samuel P Siefke/
Primary Examiner, Art Unit 1797